

RECONCILING SOCIAL AND INDUSTRIAL GOALS: A BARGAINING MODEL TO PRICING PHARMACEUTICALS

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1. Introduction

The rapid increase in pharmaceutical expenditure in many countries has generated much interest in the pricing of pharmaceuticals. Therefore many nations have some form of expenditure regulation. One example is various forms of price-cap regulations, and many nations worldwide are currently applying these in their attempts to limit the cost of pharmaceutical bills (Ess et al., 2003; Ioannides-Demos et al., 2002).

However, this use of price-cap regulation is the subject of some controversy. Opponents argue that price regulation may adversely affect incentives to develop new and better products, since producers are not adequately reimbursed for the massive investments needed to bring new drugs to the market (Danzon and Chao, 2000a).

The market for pharmaceuticals is for various reasons not fully comparable to traditional competitive markets in which other consumer products are sold, and in which the buyer is to a large extent able to ensure that he or she gets value for money. The inability of the individual to judge the merits of a drug, the fact that a patient's views may be governed by optimism rather than strict logic and the manner in which that choice is in any case largely entrusted to a third party (the physician) distort the market. The fact that governments find themselves obliged to intervene at many points distorts competitive market operation still further. In addition to specific safety nets intended to ensure access to drugs, countries have introduced many consumer protection regulations concerning the intrinsic efficacy, safety and quality of pharmaceuticals, as well as measures to raise the standard of prescribing and promote the appropriate use of drugs.

In seeking to contain the costs of drug consumption, countries impose price controls, limit reimbursement of drugs, de-list drugs considered non-essential, provide non-commercial

sources of information, and interfere with wholesale and retail margins, and may even restrict the manner in which medicines are prescribed and used (Jacobzone, 2000).

The pharmaceutical market is characterised by the almost complete absence of consumers' sovereignty; in this case, in fact, evaluation of the product cannot be related to a choice of the consumer or to a real cost-benefit evaluation of the products offered on the market. The health care literature has long recognised this problem and assumes that the consumer is ignorant about the true relationship between health care and recovered health (Zweifel and Breyer, 1997). For this reason, the demand is price inelastic. Because of the characteristics of the market for health care, the consumer seldom pays the full price of the drugs he uses. In a private market, it is the insurance company that pays for the drugs while the consumer pays an insurance premium. In a public health care system health care is usually financed through income tax and the consumer pays only a proportion of the price for the drug either in a lump sum form or as a percentage of the total cost. This creates fiscal illusion: when the consumer buys the product, the decision is made on the basis of perceived quality. In the end the total cost will have to be borne (increase in income tax/premium) but the link is not so straightforward.

In addition, the supply side of the pharmaceutical market is characterised by: 1) high investment costs in R&D that are increasing (Berndt, 2002; DiMasi et al., 2003); 2) relatively low marginal costs to produce the drug once it has been launched on the market; 3) high marketing costs (increasing) and a change in the marketing strategy: more and more consumer-perceived, given the characteristics of the demand; 4) globalisation of the industry: most of the pharmaceutical companies are concentrated in the US and a few other countries; 5) asymmetry of information on the cost, especially R&D. It is very difficult to know the real amount of resources invested to discover a new drug and also to know the benefits produced by its consumption in a specific population, therefore the regulatory authorities lack information for pricing new drugs.

This industry can use resources to finance any project it likes even if not in the field where research is most needed. Good and bad projects are paid at the same rate. A new drug has to pay for all research, whether good or bad, and in most cases we do not even know the outcome.

In the USA, prescription drug prices are largely unregulated. In most other countries, however, drug prices are regulated. National authorities have continued to implement a series of measures, both controls and incentives to influence supply of and demand for pharmaceuticals. All countries now recognise that both may be needed in order to control the growth rate of pharmaceutical expenditure.

Methods of pharmaceutical price regulation in non-US markets are heterogeneous and include, for example, direct price regulation through price controls (e.g. France and Italy),

indirect price regulation through limits on reimbursement under social insurance programmes (e.g. Germany and Japan) and indirect price regulation through profit controls (e.g. the United Kingdom) (Danzon and Chao, 2000b). Therefore, for example, a firm with 75% of its pharmaceutical sales coming from non-US markets will be more exposed to price regulation than a firm with only half its pharmaceutical sales coming from non-US markets. While this proxy of price regulation is indeed imperfect, it should, nevertheless, shed some interesting light on the differences between US and non-US pharmaceutical price-cost margins.

The pricing of drugs is a very important issue that the literature has largely investigated, even though a solution has not yet been identified. Despite a substantial empirical literature, the theoretical literature on pharmaceutical regulation is rather scant, apart from some studies applied to the Australian system (Wright 2004).

The issues at stake for determining the price of a drug are related to finding an “equitable” trade-off between the legitimate need for the industry to make a profit and full exploitation of the consumer’s surplus in a market with asymmetry of information.

One of the complicating factors in this particular field is that in so many countries a regulated, collectively financed health care sector coexists with a free and profit-driven marketplace. Both are widely regarded as desirable and defensible, yet it is evident that where the two interact, conflicts may arise; a country seeking to contain pharmaceutical expenditure will soon find itself imposing restraints on those very industrial and commercial processes which it is so anxious to promote.

The present model is an attempt to take into account the interests of both stakeholders, government and industry, in order to determine a fair price of new medicines, through a bargaining process rather than through a static model (Capri and Levaggi, 2002), based only on price differentials and incremental effectiveness.

2. The model

The model described in this paper is very general and can be used to set the price for new drugs, i.e. for active principles that have no therapeutical alternatives or for drugs that are only partially innovative, that is when a less effective alternative already exists on the market. We assume that the price is set through a bargaining process between the industry and a government agency.

The aim of this process is twofold: on the one hand it makes the drug available to those who would not be able to afford its price on the private market, and on the other it allows the pharmaceutical industry to make a bigger profit than it would obtain on the private market.

The method used in this paper is similar to Jelovac (2002) as regards definition of the objectives of the industry. In our approach, however, we consider a rather different objective function for Central Government and we assume that the drug is entirely financed by the public sector because the aim of this paper is to study pricing policies in a wider context than the one considered by Jelovac.

The bargaining process can take place if both parties have an advantage from the no bargaining solution. The necessary condition for the industry to accept the regulation is increase of its profit from the reservation level represented by the alternative of selling the drug on the private market, while for Central Government the benefit of the drug must at least offset the costs, in terms of taxation, of subsidising its consumption.

2.1. The industry's objective function

The industry wants to maximise its profit and in doing so it decides to accept the regulation only if the expected profit is at least equal to the one it would obtain by selling the product on the private market. Let's start by assuming that the drug is new and there are no therapeutical alternatives. In this case the industry, once allowed to sell the product, has a patent, i.e. a right to sell the product as a monopolist for a fixed period of time. In this environment, the firm has to define the expected demand and its elasticity for applying standard monopoly pricing rules. In a market for goods, the demand would reflect the relative benefit of the product and each consumer would buy a specific quantity according to his preferences.

In the market for pharmaceutical products, however, the setting is quite different. Health care is a primary need when demanded in order to recover from sickness, and we can assume that the consumer will buy the new good if it can afford its cost. For this reason we assume that consumers' behaviour is determined in the following setting.

Each individual has a fixed probability p of being ill and if so he can benefit from the new drug. To simplify the model, we assume that one unit of the new drug is sufficient to treat the patient. His income is then equal to Y_i but it decreases to $(1-\delta)Y_i$ if ill; however the consumer can increase it by buying the new drug. His utility can then be written as:

$$(1-p)Y_i + p(1-\delta)Y_i + p(E_N Y_i - P_N) \quad (1)$$

where P_N is the price of the drug. From (1) we can conclude that the patient will buy the drug if:

$$E_N Y_i - P_N > 0$$

where E_N is the effectiveness of the new drug, measured in standard QALYs, Y_i is the income of the i th individual and P_N is the price of the new drug.

This relationship can be interpreted as follows: the health gains will allow the consumer to increase his income so that he will be able to pay for the drug. This assumption can be justified if we think along the lines of a long-term relationship and we interpret Y as a measure of permanent rather than current income. In the short run, it might be possible for the consumer to pay more than this amount by reducing his consumption and/or by using its saving, but in the long run this behaviour cannot be sustained. Furthermore, for some consumers, there might not be a close relationship between earned income and health status², but if we abstract from these considerations and look to long-run issues, this assumption is quite plausible.

Given an income distribution and the probability of each consumer falling ill, the firm is able to derive a demand equation $D(P_N)$ whose shape depends on the income distribution and the type of illness (high/low incidence), but which will certainly be downward-sloping.

The firm faces the following linear cost function:

$$cD(P_N) + F \tag{2}$$

where c is the marginal cost and F is the fixed cost of production.

The firm sets P_N in order to maximise its profit:

$$\Pi_{P_N} = [P - cD(P_N) - F]D(P_N) \tag{3}$$

Equation (3) can be solved to obtain the optimal price P_N^* and the reservation profit of the firm:

$$\Pi_{P_N}^* = (P_N^* - c)D(P_N^*) - F \tag{4}$$

This represents the minimum profit level the firm is prepared to accept from the regulator in that market, but it is not necessarily positive.

The sign of $\Pi_{P_N}^*$ is very important from a policy point of view. A negative level means³ that the firm had foreseen from the start the intervention of the regulator in this market, i.e. the

product has been developed under the implicit assumption that only through public intervention can it be made a viable (profit-making) therapeutical alternative.

When it is positive, this level represents a threshold for accepting the regulation by the industry and can be used by the industry to accrue its negotiation power.

2.2. The benefit for Central Government

The intervention of a public regulator in the market is justified by equity reasons. The aim of the regulation is in fact to make available to the general public a drug that otherwise could be afforded only by a limited number of individuals with higher income.

Through this process, however, important savings can be achieved also by those who would have bought the drug anyway. By making the drug available to the general public, the regulation considerably widens the market for the industry and in exchange for this a price reduction can be bargained for.

Let's start by defining the equivalent of the consumer surplus in this case. We assume that a population of N individuals benefits from the drug whose cost is financed through a linear income tax at rate t . As before, each individual has a fixed probability p of being ill and if ill he can benefit from the new drug. His income is equal to Y_i but it decreases to δY_i if ill.

His utility can then be written as:

$$(1-p)(Y_i(1-t) + p[(1-\rho + E_N)Y_i(1-t)]) \quad (5)$$

where t is the linear income tax which is always equal to:

$$t = \frac{pNP_N}{\sum_{i=1}^N Y_i}$$

and the total net benefit should be equal to:

$$B = \int_{\underline{Y}}^{\bar{Y}} (1-p)(Y_i(1-t) + p[(1-\rho + E_N)Y_i(1-t)]) df(Y) \quad (6)$$

This ideal process is however quite difficult to implement for several reasons: it requires a set of information on the distribution of income and tax revenue that is extremely difficult and costly to obtain and secondly the price of the drug would depend on the level of efficiency of

each country's taxation system. The more the tax schedule is chosen optimally, the higher the benefit for the Central Government from the new drug, hence, other things being equal, the higher the price paid for the new drug.

Furthermore, from the point of view of the public regulator, this formulation of the benefit to society might not be optimal since it is related to income and tends to put more weight/benefit on those illnesses that affect rich people. For this reason, we assume that the regulator takes account of the benefit for the average individual and its relative cost.

A more plausible formulation for the benefit might be the following one:

$$AB = pNE_N \bar{Y} - T \quad (7)$$

where pN is the number of individuals that are expected to benefit from the drug and T is the cost to society, in terms of taxation of the drug, i.e. $T = pNP_N$

The net benefit can then be written as:

$$AB_N = pN(E_N \bar{Y} - P_N) \quad (8)$$

This function has a maximum for $P_N=0$ and is equal to zero if $E_N \bar{Y} = P_N$

The industry that agrees to participate in the regulation process will be faced by the following profit:

$$\Pi_{P_N} = (P_N - C)pN - F \quad (9)$$

which is increasing in P_N and is equal to zero if $P_N = c + \frac{F}{pN}$

In the previous section, however, we showed that in general the industry has a reservation profit equal to $\Pi_{P_N}^*$, which means that the minimum price it will accept is equal to $\underline{P_N^*}$.

The curves for the benefits and the profit are shown in figure one.

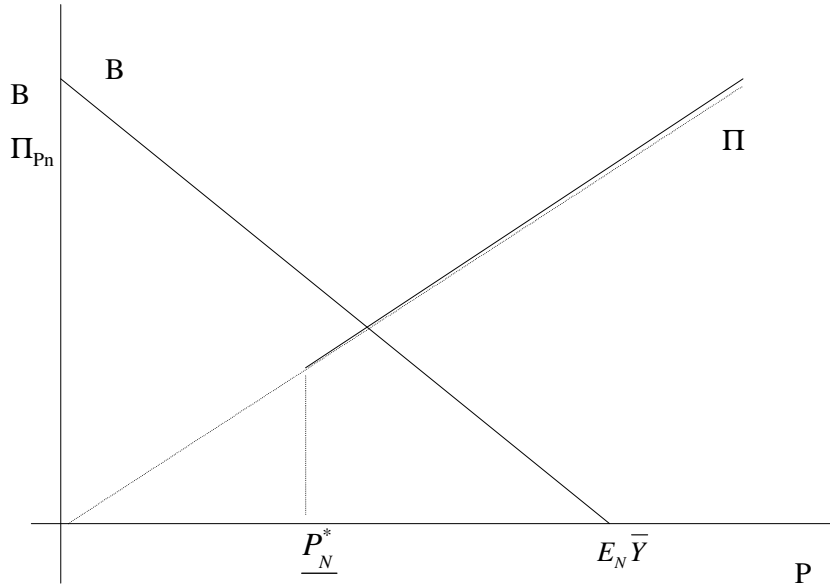


Figure one: The benefits from regulation

The line B represents the average benefit for the drug and it is downward-sloping since the benefit decreases with an increase in price. The line Π is the profit for the industry. It increases in price since the demand is predetermined in this case. P_N^* is the minimum price the industry will accept, and it might represent the cost of production of the new drug or the industry's market power. The bargaining process will determine a price in the interval $(P_N^*, E_N \bar{Y})$ according to the relative bargaining power of the two actors involved.

3. The bargaining process

The bargaining process determines the price that maximises the following function:

$$\text{Max}_{P_N} [pN(E_N \bar{Y} - P_N)]^{1-\beta} [(P_N - c)pN - F - \arg \max(\Pi_{P_N}^*, 0)]^\beta \quad (10)$$

where β is the relative bargaining power of the industry and the regulator; we can define two polar cases: for $\beta=0$ the regulator has all the power while if $\beta=1$ the industry can set the price that maximises its profit.

The bargaining power depends on several factors such as the importance of the drug in terms of the population that will benefit (p in our case), the severity of the disease that will be cured,

the number of alternatives on the market and other local factors such as the ability of the regulator and the industry in the bargaining process.

The first important thing to note is that a solution to the bargaining process can be found only if

$$\underline{P}_N^* < P_N < E_N \bar{Y}$$

The first term represents the benefit while the second one represents the reservation price for the industry. The meaning of this expression is then clear: a bargaining solution can be found when the process is profitable for both parties. When this condition is not met, the drug will not be sold on the market unless the industry is prepared to make a loss. Given the cost structure of the pharmaceutical industry we can assume that the loss will depend on unrecovered fixed costs.

From an economic point of view $E_N \bar{Y}$ has a very important role since it might represent the willingness to pay for that new drug (World Bank 2002)⁴.

The pricing rule deriving from the following process is equal to:

$$P_N^R = \beta(c + \frac{A}{pN}) + (1 - \beta)(E_N \bar{Y}) \quad (11)$$

$$A = \arg \max((P_N^* - c)D(P_N); F)$$

The formula has an interesting interpretation: apart from β , the index of the relative bargaining power of the two parties, the first term can be interpreted as joint indicator of cost and importance of the new drug, especially if the product has a viable market. In this case, in fact, $\frac{A}{pN}$ can be interpreted as a mark-up on costs that the industry can charge on its products.

The other term is the public average benefit of the drug.

The formula just presented is interesting since it shows that the knowledge of fixed costs, mainly determined by R&D investments, is not essential to the bargaining process, especially if the firm has a market without regulation.

This formula can explain the differences in the price of the drug from country to country, especially in a context where the average income differs. When the income is similar, the differences derive from a different attitude of countries to the regulation and show the relative bargaining power of the public agency.

4. Extensions to the model

In this section we consider how the model can be extended to determine the price of a new drug in settings where other competitors sell products that, although not bioequivalent, have a similar therapeutical value or can be used to treat the same condition.

If there are other competitors on the market where the new drug is introduced, the process of regulation is fairly similar, but the reservation price of the industry is lower since it no longer has a monopoly power on the private market. There are two cases that need to be treated separately, namely:

- a) there is an existing drug on the market that the regulator has decided not to reimburse;
- b) the existing drug is fully reimbursed by the public regulator.

In the first case, there are two issues that need to be addressed, the first being why the previous drug was not reimbursed since this might affect the policy for granting reimbursement. Whatever the reasons for non-inclusion of the previous drug, the application of a regulated price for the new one will have to take account of the competitor in defining the minimum profit level.

In fact, the consumer will buy the new drug in the private market, if an alternative exists with effectiveness E_O and price P if:

$$Y_i(E_N - E_O) > P_N - P_O$$

Using the same procedure as section 2, it is possible to determine the expected demand and the minimum profit. In this case the price will be equal to:

$$P_N^{RC} = \beta(c + \frac{A'}{pN}) + (1 - \beta)(E_N \bar{Y}) \quad (12)$$

$$A' = \arg \max[(P_N^{*C} - c)D(P_N^C), F]$$

In this case, no general rule exists on whether the price in this market is lower or higher than for the other drug. However the cost-effectiveness of this new product has to be greater than for the previous alternative that was not included in the list.

If, on the other hand, an alternative reimbursed drug exists, the firm has a limited demand since only the richest consumers will buy the drug and only if its effectiveness more than outweighs the cost they have to bear:

$$Y_i(E_N - E_O) > P_N$$

As for the public health gains, the new drugs permit the following net increase:

$$pN[(E_N - E_O)\bar{Y} - (P_N - P)]$$

and the price can be written as:

$$P_N^{RC} = \beta(c + \frac{A''}{pN}) + (1 - \beta)[(E_N - E_O)\bar{Y}] + P \quad (13)$$

$$A'' = (P_N^{*C} - c)D(P_N^C)$$

In this case, the industry has a much lower bargaining power, as one might expect. On the market there is in fact a valid alternative whose effectiveness has already been proved and accepted by the regulator. The industry can charge a higher price that is strictly related to the differential in its effectiveness. This principle is becoming quite important in some public health care systems that adopt cluster reference pricing.

5. The empirical relevance of the model: some applications

In this session we discuss the empirical relevance of our model with references to some pricing policies that have been recently proposed to regulate the drug market.

In particular, we will refer to the following ones:

- drug pricing for low income countries
- international reference pricing (Garcia Marinos et al., 2004)
- clustering reference price

5.1. Low income countries

In the recent past the problem of setting the price for drugs in low-income countries has been widely debated both from an economic and a political point of view (Scherer and Watal, 2002; Danzon and Towse, 2003). The most common solution is a substantial reduction in the average market price of the drug that the industry sells to low-income countries along with some measures to avoid parallel imports.

This policy is usually seen as a liberal contribution of drugs companies towards low-income countries, but this might not be the case as our model clearly points out.

For low-income countries, two factors contribute to a reduction in price:

- the mark-up is going to be limited since nobody would probably be able to afford to pay for the drug;
- the public benefit, in terms of accrued income from the increased QALY recovered via the drug, is fairly low due to a low average income.

For a low-income country, setting a lower price does not necessarily mean that the industry has a low negotiation power; the decrease in price might depend on the ability of the country to pay.

In this case, $\frac{A}{pN}$ can even be set to zero since it might be reasonable to assume that the market is not fundamental for the industry which might decide to allocate its cost in R&D to the most profitable markets. In this context, in fact, the marginal cost might become the only relevant decision variable for the industry that charges the minimum possible price.

It is interesting to note, however, that this might not necessarily mean that the industry is not able to exploit the ability to pay of the country considered. For a low-income country, a possible representation might be the following figure two.

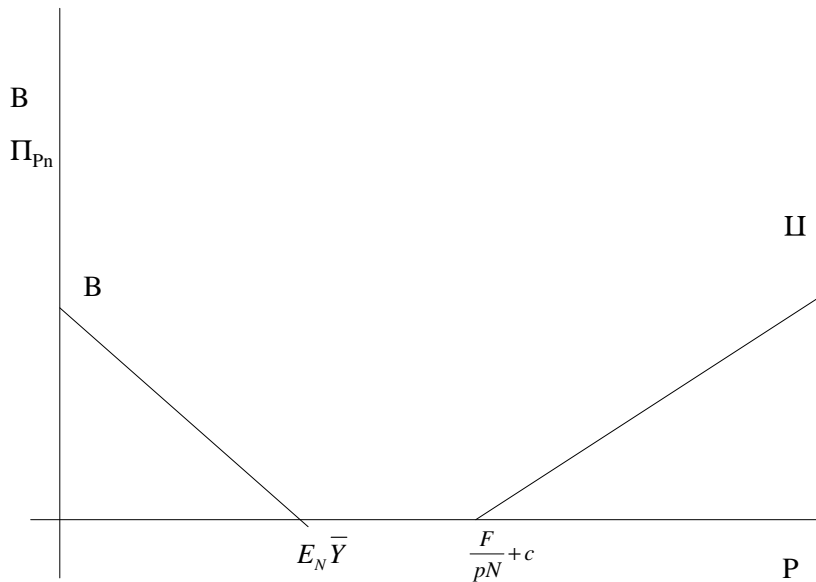


Figure two: Benefits for low-income countries

In this case, the bargaining process would not have any reason to exist, since the price of entering the bargaining process is not met by the ability of the country to pay.

However, given the relatively low importance of this market for the industry and the extreme relevance of the drug for the country, the industry might agree to set $\frac{F}{pN}$ to zero and offer the drug for a price higher than c and as close as possible to $E_N \bar{Y}$.

A better measure of how much the industry contributes to the wellbeing of that specific low-income country is the following index that can be derived from the following equation:

$$PAD = \frac{P_N}{E_N \bar{Y}}$$

PAD means “Price and Affordability of Drug”.

The smaller the index, the more the industry is making a contribution towards the welfare of that nation. It is interesting to note that this index could be higher than one. In this case there would be exploitation of the market since the benefit would be lower than the cost.

5.2. Reference pricing

Reference-based pricing is a direct cost-sharing measure whereby the amount of money reimbursed for a drug is determined by the cost of the lowest priced "interchangeable agent" in that therapeutic class of drugs; any cost above that is borne by the patient (Kanavos and Reinhardt, 2003).

Pharmaceutical companies remain free to charge more than the reference price; however, since the patient must pay the difference, demand is highly elastic above the reference price, leading most companies to drop their prices to the reference price. There is also a so-called international reference pricing, a policy by which the price of a drug in a predefined set of countries is set according to the average price in those countries. This policy is in line with the model presented in this paper provided that the income has a low cross-country variation. Clustering reference price, on the other hand, refers to the policy of pricing at the average cost some drugs that are interchangeable.

This policy can be explained by equation (13) of our model

The implicit assumption is that a cluster of drugs has the same effectiveness (E_N) and the same marginal cost. If this is the case, their regulated price has to be the same.

It is however important to note that, in the logic of our model, this pricing rule is fully justified only in two specific cases:

- a) the willingness to pay in the private market would lead both products to have the same profit level;
- b) the minimum price accepted by the industry is equal to $\frac{F}{pN} + c$ and both drugs have the same cost;
- c) the industry has a full monopoly power and sets the price equal to the net average benefit of the drug.

6. Conclusions

In this paper we present a simple bargaining process to set the price of drugs in the context of a public health care system.

The model presented in this article uses an approach to explain the bargaining process between the industry and the public regulator. The need for regulation arises for several reasons:

- it might be required to subsidise the industry because the cost of R&D is so high that the private demand on the private market would not be sufficient to break even;
- it might be inspired by equity reasons. In this case, the regulator enters the market to grant a substantial reduction in the cost of the drug and to make it available to those who would not be able to afford its cost. The regulation process is viable because the production volume increases and, given the nature of drug costs, this permits an increase in profits.

The benefits of this process are shared between the regulator and the industry according to the market power of the two actors.

In particular, we note that if an alternative exists on the market, i.e. a comparator with similar or equivalent efficacy, the new drug has to be more cost-effective to enter, and in any case its cost- effectiveness represents the upper limit to its price.

Our model explains several features of the drug regulation process. It shows how the policy of selling drugs to lower-income countries at very low prices can still be interpreted within a bargaining model and such a low price does not necessarily mean that the industry has no power in the regulation process. In this light the rationale of policies such as reference pricing and clustering also emerges.

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Notes

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² Some workers might be protected by sickness funds that pay the difference between the earned salary and what the individual would have earned if he was able to work throughout the whole period.

³ If we exclude the case in which the firm has made a mistake in planning.

⁴ The World Bank considers that a health intervention is cost-effective if it buys each year of healthy life for less than the per-capita GNP of the country.